Remarks

Applicant has carefully considered this Application in connection with the Examiner's Action, and respectfully requests reconsideration of this Application in view of the foregoing amendment, and the following remarks.

Applicant has amended Claims 1, 5, 7, 8, 9, 13, and 15, and canceled Claims 2-4, 6, 10-12, and 14. Accordingly, Claims 1, 5, 7, 8, 9, 13, and 15 are presently pending in the Application, with Claims 1, and 15 being the independent claims.

I. Rejection under 35 U.S.C. § 112, Second Paragraph

Claims 1-15 stand rejected under 35 U.S.C. § 112, Second Paragraph, for being indefinite and for failing to particularly point and distinctly claim the subject matter which the Applicant regards as the invention. (Office Action page 2).

A. In particular, the Examiner asserts that the phrase "a mixture in a divided form" in the Claims is ambiguous. Applicant respectfully disagrees. Claims 1, 5, and 15 have been amended to replace the phrase "a mixture in a divided form" with the term "a mixture". As used in the application, the term "mixture" refers to "a powder, a granulate, a grind, or a pulver of particles" and is found on at least page 2 of the specification as filed. In this context, one ordinary skill in the art would understand what a "mixture" means a powder, a granulate, a grind, or a pulver of particles. Thus, the metes and bounds of the claims are adequately defined. In light of the amended claim language, Applicant respectfully requests that the Examiner reconsider and withdraw the rejection of Claims 1-15 under 35 U.S.C. § 112, Second Paragraph.

B. Claims 2-4 stand rejected under 35 U.S.C. § 112, Second Paragraph as being indefinite for failing to particularly point out and distinctly claim subject matter, specifically whether or not the dissolution rate is in vitro before administering the drug to a subject or in vivo after administering the drug. Claims 2-4 have been cancelled.

C. Claims 5-9 stand rejected under 35 U.S.C. § 112, Second Paragraph as being indefinite for failing to particularly point out and distinctly claim subject matter, specifically how a suspension can be a crushed tablet without a liquid. Claims 5, 7-9 have been amended to more clearly state that the "oral suspension" is not merely a

crushed tablet but rather a solid "mixture" and a "beverage," support for which can be found on at least page 2 of the specification as filed. In light of the amended claim language, Applicant respectfully requests that the rejection of Claims 5, 7-9 under 35 U.S.C. § 112 be reconsidered and withdrawn.

II. Rejection of Claims under 35 U.S.C. § 103(a)

The Examiner has rejected Claims 1–15 under 35 U.S.C. § 103(a) as being unpatentable over De Bruijn (WO0010526) in view of Patel (US 20030180352) and in further view of Achong (US 20040162273).

DeBruijn is directed to a pharmaceutical composition for administering an acid sensitive active ingredient that is poorly soluble.

Patel is directed to solid carriers for improved delivery of active ingredients in a pharmaceutical composition to mask the taste of unpalatable active ingredients.

Achong is directed to a powder pharmaceutical composition that can also be formulated to contain aesthetically pleasing flavor and sweetener ingredients when dissolved in a host of liquids including but not limited to apple juice.

In making the Section 103 (a) rejection, the Examiner cites DeBruijn as teaching a composition for administering an acid sensitive active ingredient that is poorly soluble and Patel as teaching solid carriers to improve the delivery of active ingredients in pharmaceutical ingredients by masking the taste. The Examiner states that one skilled in the art would be motivated to combine DeBruijn and Patel to mask the unpleasant taste for the drugs disclosed.

Applicant respectfully submits that neither DeBruijn nor Patel teach, suggest, or provide motivation to use a crushed tablet of tegaserod, or apple juice as a beverage as recited in Applicant's Claims 1 and 15. The use of crushed tablets of tegaserod containing a known and fixed amount of active ingredient — which is not disclosed or suggested in either DeBruijn or Patel — is an alternative method of tegaserod administration which is especially suitable for a patient's use at home.

Applicant also respectfully submits that it has also found that while tegaserod can be administered in a crushed tablet form in various media, apple juice has an

unexpected advantage, and superior dissolution profile when compared to other masking agents such as orange juice and apple sauce. See Carrier et al. "*Stability and Compatibility of Tesgaserod from Crushed Tablets Mixed in Beverages and Food*" American Society of Health-System Pharmacists, Inc. (2004), Pages 1138 (3d column), 1140 (3d column), and 1141 (middle column) (Attached hereto as Exhibit A). Applicant has discovered that the dissolution of crushed tablets of tegaserod in apple juice was complete in five minutes and that the tegaserod was stable in apple juice for up to one hour at room temperature and up to three days when stored in a refrigerator. (See Carrier, Page 1140) Moreover, as stated above, the use of a crushed tablet in the suspension containing a known and fixed amount of active ingredient makes it easy to prepare and suitable for a patient's use at home.

In making the Section 103 (a) rejection, the Examiner turns to Achong for teaching a powder pharmaceutical composition that can be formulated to contain aesthetically pleasing flavor and sweetener ingredients when dissolved in beverages such as cold water and apple juice. The Examiner states that one skilled in the art would be motivated to combine Achong with DeBruijn and Patel to use apple juice to mask the unpleasant taste for the drugs disclosed.

However, there is no teaching, suggestion, or motivation in Achong to use the superior dissolution properties of crushed tablets of tegaserod in apple juice as recited in Applicant's independent Claims 1 and 15. Nor does Achong recognize that apple juice is preferable to a host of other aesthetically pleasing flavor and sweetener ingredients. Therefore, Applicant respectfully asserts that the combination DeBruijn, Patel, and Achong does not allow for a predictable use of the superior dissolution properties of crushed tablets of tegaserod in apple juice.

So, thus, in view of the foregoing remarks, the cited references of DeBruijn, Patel and Achong do not, singularly or in combination, teach, or suggest each and every claim limitation of Applicant's independent Claims 1 and 15, nor is there a predictable use of the elements to support the Examiner's rejection of Claims 1 and 15 under 35 U.S.C. § 103(a). Further, the limitations of Claim 1 is inherited by its respective

dependent Claims 5, 7, 8, 9, 13, and are therefore not obvious by the references, either singularly or in combination.

In view of the above, Applicant respectfully requests the Examiner reconsider and withdraw the rejection of the claims under 35 U.S.C. §103.

III. Information Disclosure Statement

The Examiner has noted that the Information Disclosure Statement filed on 09/27/2005 did not include "a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed." Applicant submits that that the requested foreign patent documents are included, and respectfully requests that the Examiner determine that the Information Disclosure Statement filed on 09/27/2005 complies with 37 C.F.R. 1.98(a)(2).

IV. Conclusion

In view of the foregoing, Claims 1, 5, 7, 8, 9, 13, and 15 are in condition for allowance, and Applicant earnestly solicits a Notice of Allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this Application, the Examiner is invited to telephone the undersigned at the number provided. Prompt and favorable consideration to this Amendment and Reply is respectfully requested.

Respectfully submitted,
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